



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/962,421	10/31/1997	EUGENIO A. CEFALI	20720-95585	8845

7590 12/30/2005  
Karen J Messick Esq  
Kos Pharmaceuticals Inc  
2200 North Commerce Parkway  
Suite 300  
Weston, FL 33326

EXAMINER

HAWES, PILI ASABI

ART UNIT	PAPER NUMBER
----------	--------------

1615

DATE MAILED: 12/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 08/962,421	<b>Applicant(s)</b> CEFALI ET AL.	
	<b>Examiner</b> Pili A. Hawes	<b>Art Unit</b> 1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. ____   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____.   | 6) <input type="checkbox"/> Other: ____.                                    |

## DETAILED ACTION

### *Summary*

Claims 1-4 are pending in this action. Claims 1-4 are rejected.

### *Priority*

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. [1] as follows:

The later-filed application must be an application for a patent for an invention, which is also disclosed, in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 08/814974 now US Patent 6129930, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The instant claims 1-4 recite an intermediate release composition comprising nicotinic acid, in which the nicotinic acid is released over a stair stepped absorption profile. However, the particular stair stepped absorption profile recited by instant claims are not supported by the parent application. Thus, claims 1-4 do not receive benefit of the priority date of the parent application. The only reference to a rate

Art Unit: 1615

of release that the claims or the specification make is a sustained release rate in which between about 2-25% of the nicotinic acid is released per hour. This general teaching does not support the specific recitation of up to 19% of nicotinic acid absorbed between 1-4 hours in the first phase, between 78-100% absorbed between 5-9 hours in the second phase, and between 86-100% absorbed by about 9 hours in the third phase.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6406715.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

As discussed above, Applicant does not receive benefit of the filing date of the CIP parent US 6129930. Thus the filing date of the instant application is 10-31-1997. The filing date of the prior art reference is 10-31-1997, and the prior art reference claims benefit of priority applications dated back to 09-20-1993. The reference names one inventor in common with the instant application, while the instant application names two inventors. Thus this prior art reference is "by another" and has a prior effective U.S. filing date, which is earlier than the instant applications filing date.

Cefali teaches compositions that afford intermediate release of nicotinic acid, and that are used for the treatment of hyperlipidemia (col. 1, lines 20). The instant claims are drawn to a method of treating hyperlipidemia with an intermediate release composition of nicotinic acid. The prior art reference also teaches the composition to have a stair-stepped absorption profile (col. 5, line 31). The reference further teaches that the composition releases "at least the majority" of the composition between 5 and 9 hours (col. 5, lines 17-20). The reference also describes three separate absorption phases: A, B and C (col. 8, lines 1-13). Phase A occurs within 1-4 hours, phase B between 4-8 hours, and phase C between 5-9 hours (col. 8, lines 15-19). Table 1 discloses that up to about 19% of the composition is absorbed in phase A, and between 78-100% is absorbed in phase B, with the remainder being absorbed in phase C (col. 8, lines 20-25). Table 1 shows that 90.7 % is absorbed in phase B, this is about 91% as is recited in instant claims. Table 1 also discloses the same absorption rate ranges for each phase as claimed in claim 3. Table 1 also discloses the limitations of claim 4, in that the

Art Unit: 1615

% dose absorbed in phase A was 3.3% in 2.3 hours, and in phase B was 19% in 7.3 hours.

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pili A. Hawes whose telephone number is 571-272-8512. The examiner can normally be reached on 8-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

P.A. Hawes  
Examiner-1615

THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1615